

## REMARKS

### A. Claims 1, 3-6, 64, 66-69, 70, and 72-75 Are Novel over Kontos '539

Claims 1, 3-6, 64, 66-69, 70, and 72-75 stand rejected under section 102(b) over Kontos '539 (US 5,890,539). Applicant traverses.

#### 1. Independent Claim 1

Claim 1 has been amended to recite:

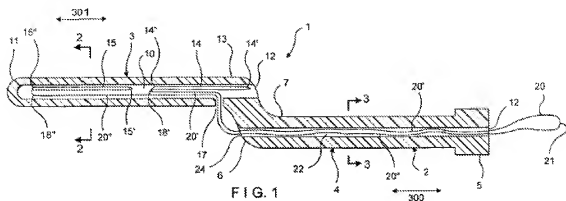
- a body having a leading end and a trailing end, the leading end of the body being the first end of the body that will be inserted into a patient during a procedure;
- a lumen extending from a first lumen opening formed in the body to a second lumen opening formed in the body;
- a first needle guide channel extending from a first needle guide channel opening formed in the body to a second needle guide channel opening formed in the body; and
- a needle having a leading end and a trailing end, the trailing end of the needle being connected to a length of suture, the leading end of the needle being the first end of the needle that will penetrate tissue during a procedure, the needle being and backloaded into the first needle guide channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle, the length of suture being threaded through the lumen such that the needle will be advanced out of the first needle guide channel by pulling on a portion of the length of suture that is unsurrounded by the medical device and positioned outside of the body ....

The language "by the medical device" has been amended for clarity, and for no other reason.

The remaining underlined language has been added to distinguish Kontos '539, and for no other reason.

The claimed leading end of the body is "the first end of the body that will be inserted into a patient during a procedure[.]" In the Kontos '539 device, the leading end is distal end 11. This end is the first end of the device that will be inserted into a patient during a procedure, as shown

in Figure 12. Consequently, the trailing end of the body would be end 5—the rightmost end shown in Figure 1:



The claimed leading end of the needle is “the first end of the needle that will penetrate tissue during a procedure[.]” In the Kontos ‘539 device, the leading end of needle 14 is proximal end 14’ and the leading end of needle 15 is proximal end 15’. The trailing ends of these needles are distal end 14’’ and distal end 15’’, respectively.

As the Kontos ‘539 figures show, neither needle 14 or needle 15 is backloaded into any channel such that the trailing end of the flexible tube 4 (*i.e.*, end 5) is closer to the trailing end of that needle (*i.e.*, end 14’’ or end 15’’) than to the leading end of that needle (*i.e.*, end 14’ or end 15’), as recited by amended claim 1. Instead, for the Kontos ‘539 device, the opposite is true: the trailing end 5 of the flexible tube 4 is closer to the leading ends 14’ and 15’ of each needle than to the trailing ends 14’’ and 15’’ of each needle. Accordingly, claim 1 is novel over Kontos ‘539, and the rejection of claims 1 and 3-6 should be withdrawn.

## 2. Independent Claim 64

Independent claim 64 has been amended to recite:

a body having a leading end and a trailing end, the leading end of the body being the first end of the body that will be inserted into a patient during a procedure;

- a lumen extending from a first lumen opening formed in the body to a second lumen opening formed in the body, the lumen being substantially centered within the body;
- a first needle guide channel extending from a first needle guide channel opening formed in the body to a second needle guide channel opening formed in the body; and
- a needle having a leading end and a trailing end, the trailing end of the needle being connected to a length of suture, the leading end of the needle being the first end of the needle that will penetrate tissue during a procedure, the needle being and backloaded into the first needle guide channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle, the length of suture including a portion that is unsurrounded by the medical device and positioned outside of the body ....

The language “by the medical device” has been amended for clarity, and for no other reason.

The remaining underlined language has been added to distinguish Kontos ‘539, and for no other reason.

As explained above, Kontos ‘539 does not teach a needle backloaded into any channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle, as recited by amended claim 64. Accordingly, claim 64 is novel over Kontos ‘539 and the rejection of claims 64 and 66-69 should be withdrawn.

### 3. Independent Claim 70

Independent claim 70 has been amended to recite:

- a body having a leading end and a trailing end, the leading end of the body being the first end of the body that will be inserted into a patient during a procedure;
- a lumen extending from a first lumen opening formed in the body to a second lumen opening formed in the body;
- a first needle guide channel extending from a first needle guide channel opening formed in the body to a second needle guide channel opening formed in the body; and

a needle having a leading end and a trailing end, the trailing end of the needle being connected to a length of suture, the leading end of the needle being the first end of the needle that will penetrate tissue during a procedure, the needle being and backloaded into the first needle guide channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle, the length of suture including a portion that is unsurrounded by the medical device and positioned outside of the body, and the length of suture being threaded through the lumen such that the needle will advance in a forward direction out of the first needle guide channel when the length of suture is pulled in a rearward direction.

The clause “the length of suture including a portion that is unsurrounded by the medical device and positioned outside of the body” was added to distinguish Ainsle as explained below, and for no other reason. The remaining changes were made to distinguish Kontos ‘539, and for no other reason.

As explained above, Kontos ‘539 does not teach a needle backloaded into any channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle, as recited by amended claim 70. Accordingly, claim 70 is novel over Kontos ‘539 and the rejection of claims 70 and 72-75 should be withdrawn.

**B. Claims 31-41 Are Novel over Kontos ‘555**

Claims 31-41 stand rejected under section 102(b) over Kontos ‘555 (US 5,997,555). Applicant traverses.

Independent claim 31 has been amended to recite:

- a body having a leading end and a trailing end, the leading end of the body being the first end of the body that will be inserted into a patient during a procedure;
- a lumen extending from a first lumen opening formed in the body to a second lumen opening formed in the body;
- a first needle guide channel extending from a first needle guide channel opening formed in the body; and

a needle having a leading end and a trailing end, the trailing end of the needle being connected to a length of suture, the leading end of the needle being the first end of the needle that will penetrate tissue during a procedure, the needle being and backloaded into the first needle guide channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle, the length of suture being threaded through the lumen such that when a portion of the length of suture that is unsurrounded by the medical device and positioned outside of the body is pulled in a first direction away from the body, the needle is advanced out of the first needle guide channel in a second direction, the first direction having a positive longitudinal component and the second direction having a negative longitudinal component.

The language “by the medical device” has been amended for clarity, and for no other reason. The remaining underlined language has been added to distinguish Kontos ‘555, and for no other reason.

The claimed leading end of the body is “the first end of the body that will be inserted into a patient during a procedure[.]” In the Kontos ‘555 device, the leading end is the leftmost end shown in Figure 1. This end is the first end of the device to be inserted into a patient during a procedure, as shown in Figure 6. Consequently, the trailing end of the body is the rightmost end shown in Figure 1.

The claimed leading end of the needle is “the first end of the needle that will penetrate tissue during a procedure[.]” In the Kontos ‘555 device, the leading end of either needle 37 is the rightmost end of the needle shown in Figure 2. The trailing end of each needle 37 is the end connected to the suture 41 (described as the “distal ends” of the needles at col. 5, lines 60-61).

As the Kontos ‘555 figures show, neither needle 37 is backloaded into channel 32 such that the trailing end of the flexible tube 16 (*i.e.*, the end on the right of Figure 1) is closer to the trailing end of that needle than to the leading end of that needle, as recited by amended claim 31. Instead, for the Kontos ‘555 device, the opposite is true: the trailing end of the flexible tube 16 is closer to the leading end of each needle 37 than to the trailing (or distal) end of each needle 37.

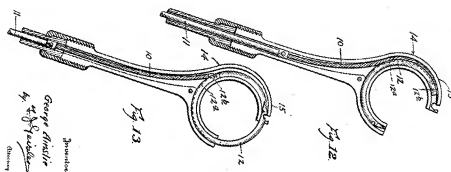
Accordingly, claim 31 is novel over Kontos '555, and the rejection of claims 31-41 should be withdrawn.

**C. Claims 70-75 Are Novel over Ainslie**

Claims 70-75 stand rejected under section 102(b) over Ainsle (US 1,822,330). Applicant traverses.

The Office has read “flexible cable 10” of Ainsle on the “length of suture” recited in independent claim 70. Claims 70 has been amended to recite “the length of suture including a portion that is unsurrounded by the medical device and positioned outside of the body[.]”

There is no portion of flexible cable 10 of the Ainsle device that is unsurrounded and positioned outside of “needle casing 14” of Ainsle (which the Office construes as the claimed body). The portion of flexible cable 10 outside of needle casing 14 is surrounded by the balance of Ainsle’s suturing instrument. This is clear from Figs. 12 and 13 of Ainsle, reproduced below:



Accordingly, claim 70 is novel over Ainsle, and the rejection of claims 70-75 should be withdrawn.

**D. Claims 2, 65, and 71 Are Patentable over the Asserted Combination**

Claims 2, 65, and 71 stand rejected as obvious over Kontos '539 in view of Kontos '555. Applicant traverses. Each of these dependent claims depends from an independent claim that is

novel over Kontos '539 for the reasons provided above, and is therefore novel over Kontos '539 for at least the same reason. Kontos '555 fails to cure the deficiency of Kontos '539.

**E. Claims 7, 10, 11, 76, 79, 80, 81, and 83-87  
Are Patentable over Kontos '539**

Claims 7, 10, 11, 76, 79, 80, 81, and 83-87 stand rejected as obvious over Kontos '539. Applicant traverses. Each of dependent claims 7, 10, 11, 76, 79, and 80 depends from an independent claim that is novel over Kontos '539 for the reasons provided above, and is therefore novel over Kontos '539 for at least the same reason. Nothing in Kontos '539 suggests the missing limitation. Therefore, these dependent claims are nonobvious over Kontos '539 as well.

Independent claim 81 has been amended to distinguish Kontos '539 and now recites:

- a body;
- a lumen extending from a first lumen opening formed in the body to a second lumen opening formed in the body;
- a first needle guide channel extending from a first needle guide channel opening formed in the body to a second needle guide channel opening formed in the body;
- a first needle connected to a first length of suture and backloaded into the first needle guide channel, the first length of suture being threaded through the lumen such that the first needle will be advanced out of the first needle guide channel by pulling on the first length of suture;
- a second needle guide channel extending from a third needle guide channel opening formed in the body to a fourth needle guide channel opening formed in the body; and
- a second needle connected to a second length of suture and backloaded into the second first needle guide channel, the second length of suture being separate from the first length of suture, and the second suture being threaded through the lumen such that the second needle will be advanced out of the second first needle guide channel by pulling on the second length of suture.

where the first needle is the only needle backloaded into the first needle guide channel prior to a procedure and the second needle is the only needle backloaded into the second needle guide channel prior to a procedure.

Kontos '539 fails to teach or suggest one first needle in a first needle guide channel, the first needle being connected to a first length of suture, and one second needle in a second needle guide channel, the second needle guide channel connected to a second length of suture that is *separate from* the first length of suture, where the first needle is the *only* needle backloaded into the first needle guide channel *prior to a procedure* and the second needle is the *only* needle backloaded into the second needle guide channel *prior to a procedure*. The only embodiment in Kontos '539 involving multiple needle guide channels (though they fail to be needle guide channels extending between two needle guide channel openings as claimed) is the embodiment shown starting in Figure 17, where *multiple* needles are stacked in a given channel prior to a procedure. For this reason, independent claim 81 is patentable over Kontos '539, and the rejection of claims 81 and 83-87 should be withdrawn.

**F. Claims 8, 9, 77, 78, 82, 88, and 89  
Are Patentable over the Asserted Combination**

Claims 8, 9, 77, 78, 82, 88, and 89 stand rejected as obvious over Kontos '539 in view of Kontos '555. Applicant traverses. Each of these dependent claims depends from an independent claim that is novel over Kontos '539 for the reasons provided above, and is therefore novel over Kontos '539 for at least the same reason. Kontos '555 fails to cure the deficiency of Kontos '539.



**G. Conclusion**

Applicant respectfully submit that pending claims 1-11, 31-41 and 64-91 are in condition for allowance. The Office is invited to contact the undersigned attorney at (512) 536-3031 with any questions.

Respectfully submitted,

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